AMENDMENT AND RESPONSE TO OFFICE ACTION

AND PETITION FOR EXTENSION OF TIME

U.S. Serial No.: 09/932,503

Page 4

Amendments in the Claims

- 1. (Withdrawn) A particle, comprising:
 - (1) a core, comprising calcium phosphate;
 - (2) a therapeutic agent associated with the core; and
 - (3) a layer comprising casein at least partially covering the core.
- 2. (Withdrawn) The particle of claim 1, wherein the therapeutic agent is selected from the group consisting of insulin, Alpha-1-Antitrypsin, Human Growth Hormone (HGH); Erythropoeitin (EPO), Steroids, drugs to treat osteoporosis, blood coagulation factors, anticancer drugs, antibiotics, lipase, garanulocyte-colony stimulating factor (G-CSF), Beta-Blockers, anti-asthma, anti-sense oligonucleotides, therapeutic antibodies, DNase enzyme for respiratory diseases, anti-inflammatory drugs, anti-virals, anti-hypertensives, cardiotherapeutics, antiarrythmia drugs, gene therapies; diuretics, anti-clotting chemicals, and any combination thereof.
- 3. (Withdrawn) The particle of claim 1, wherein the particle size ranges from about 300 nm to about 10 microns.
- 4. (Withdrawn) The particle of claim 1, wherein the therapeutic agent is at least partially coated on the outside of the core, at least partially encapsulated within the core, or a combination of both.
- 5. (Withdrawn) The particle of claim 1, further comprising a surface modifying agent at least partially coated on the outside of the core, at least partially embedded within the core, or a combination of both.
- 6. (Withdrawn) The particle of claim 5, wherein the surface modifying agent is selected from the group consisting of basic sugars, modified sugars, polyethylene glycol, cellobiose,

AMENDMENT AND RESPONSE TO OFFICE ACTION

AND PETITION FOR EXTENSION OF TIME

U.S. Serial No.: 09/932,503

Page 5

oligonucleotides, carbohydrates, carbohydrate derivatives, macromolecules with carbohydratelike components, and combinations thereof.

- 7. (Withdrawn) A therapeutic composition comprising the particle of claim 1 and a pharmaceutically acceptable excipient.
- 8. (Withdrawn) The therapeutic composition of claim 7, wherein the therapeutic agent is insulin.
- 9. (Withdrawn) A therapeutic composition suitable for oral delivery of insulin, comprising:
 - (1) a core comprising calcium phosphate;
 - insulin and polyethylene glycol associated with the core; wherein the insulin and polyethylene glycol are at least partially encapsulated within the core;
 - (3) a capsule comprising casein at least partially covering the core; wherein the capsule is combined with a pharmaceutically acceptable excipient.
- 10. (Withdrawn) A method of preparing one or more particles having calcium phosphate complexed with a therapeutic agent to form a particle, wherein the particle is encapsulated by casein, comprising:
 - (a) reacting a soluble calcium salt, a soluble phosphate salt, and the therapeutic agent to form a mixture;
 - (b) dispersing the mixture in a solution of casein.
- 11. (Withdrawn) The method of claim 10, wherein the reacting (a) further comprises:
 - (i) mixing the therapeutic agent with a surface modifying agent; and
 - (ii) reacting the soluble calcium salt and the soluble phosphate salt with the therapeutic agent and surface modifying agent to form the mixture.

AMENDMENT AND RESPONSE TO OFFICE ACTION AND PETITION FOR EXTENSION OF TIME

U.S. Serial No.: 09/932,503

Page 6

- 12. (Currently Amended) A method for delivering a therapeutic amount of a therapeutic agent to a patient in need thereof, comprising orally delivering one or more particles of claim 1. comprising:
 - (1) a core, comprising calcium phosphate;
 - (2) a therapeutic agent associated with the core; and
 - (3) a layer comprising casein at least partially covering the core.